

II. REMARKS

Claims 1 and 13 have been amended to recite “each of the shutters including a first through-hole respectively formed therein” as supported by Figure 5 of Applicant’s disclosure as originally filed.

The present amendment adds no new matter to the above-captioned application.

A. The Invention

The present invention relates to a blood access device for hemodialysis that is of a no-needle type. More specifically, in accordance with an embodiment of the present invention, a no-needle blood access device for hemodialysis is provided that includes the limitations recited by independent claim 1. In accordance with another embodiment of the present invention, a no-needle blood access device for hemodialysis is provided that includes the limitations recited by independent claim 13.

With the invention, the artery or vein will be in communication with the dialyzer without leakage of blood, so that hemodialysis can be done without a caregiver. The device of the present invention provides these features with a relatively simple structure, enabling manufacture at low cost, and ease of handling.

B. The Rejections

Claims 1, 3, 7, 8, 10, 11 and 13 stand rejected under 35 U.S.C. § 102(b) as anticipated by Kawamura (U.S. Patent 6,231,541 B1, hereafter the “Kawamura’541 Patent”).

Claims 1 and 13 also stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claim 1 of U.S. Patent 6,524,273 B2 to Kawamura (hereafter, the “Kawamura’273 Patent”).

Applicant respectfully traverses the present rejections and requests reconsideration

and allowance of the above-captioned application for the following reasons.

C. Applicant's Arguments

i. The Section 102 Rejection

Anticipation under 35 U.S.C. § 102 requires showing the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). In this case, the Examiner has failed to establish a prima facie case of anticipation against the claimed invention because the Kawamura'541 Patent does not teach, or suggest, "a pair of shutters... each of the shutters including a first through-hole respectively formed therein" as recited by independent claims 1 and 13.

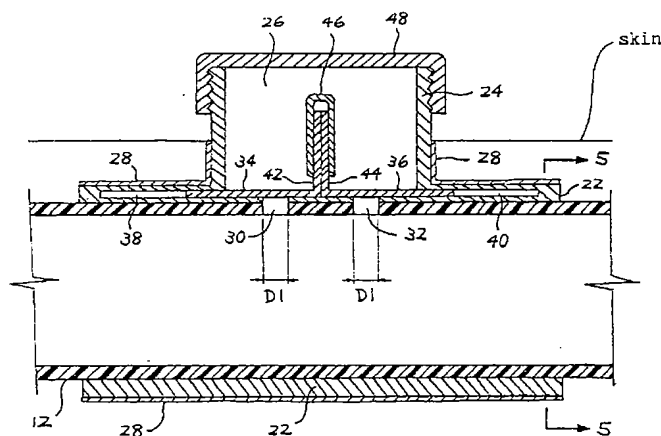
ii. The Kawamura'541 Patent

The Kawamura'541 Patent discloses a "no-needle blood access device for hemodialysis and no-needle connecting cannula assembly" that, as shown in Figures 6 and 10, includes (a) an artificial conduit (12) whose opposite ends are anastomosed to a targeted artery or vein; and (b) a metallic body (20), the body including a cylindrical horizontal portion (22) covering the entire circumference of the conduit or an arcuate-shaped horizontal portion (50) covering at least an upper half of the circumference of the conduit, and a cylindrical vertical portion (24) connected to approximately the center of the upper part of the horizontal portion so as to be disposed perpendicular to the horizontal portion and defining a well (26) therein, wherein the horizontal portion is provided at the part located at the bottom of the well with a first pair of apertures (30, 32), and the conduit is provided at the corresponding part with a second pair of apertures (30, 32), whereby the well is in communication with the conduit through the apertures; and (c) a pair of shutters (34, 36)

slidably housed within opposed pockets formed in the upper part of the horizontal portion respectively and arranged such that they can be opened and closed (See Abstract of the Kawamura'541 Patent). The Kawamura'541 Patent also discloses that when the shutters (34, 36) are opened, the well (26) is brought into communication with the conduit (12), and when the shutters are closed, the well is brought out of communication with the conduit (See Abstract).

As shown in Figure 2 of the Kawamura'541 Patent, the shutters (34) and (36) have no holes formed therein. Figure 2 of the Kawamura'541 Patent is reproduced below for the Examiner's convenience.

FIG. 2



As is evident from Figure 2, the Kawamura'541 Patent does not teach, or even suggest, "a pair of shutters... each of the shutters including a first through-hole formed therein" as recited by independent claims 1 and 13 of the above-captioned application. In fact, if the shutters (34) and (36) were modified to include holes formed therein, they would not operate as intended to bring the well (26) out of communication with conduit (12) when in the closed state (see Figure 2 and col. 4, lines 43-56). Because such a modification of the

shutters disclosed by the Kawamura'541 Patent would obliterate an essential feature of the device disclosed by the Kawamura'541 Patent, it would not be obvious to add through-holes to the shutters (34) and (36) of Kawamura's device. See, e.g., McGinley v. Franklin Sports Inc., 60 U.S.P.Q.2d 1001, 1010-11 (Fed. Cir. 2001). Furthermore, the addition of holes to the shutters (34) and (36) would serve no purpose when the shutters (34), (36) are in the open state (see Figure 10) because the shutters (34), (36) are then disposed in pockets (38) and (40), respectively.

For all of the above reasons, the Kawamura'541 Patent cannot anticipate, or render obvious, the subject matter of independent claims 1 and 13.

iii. The Obviousness-type Double Patenting Rejection

The Federal Circuit has ruled that in order to justify a double patenting rejection an analysis of the claims at issue is required, and not an analysis limited to the disclosure of the patents whose claims are relied upon to demonstrate double patenting. General Foods Corp. v. Studiengesellschaft Kohle mbH, 23 U.S.P.Q.2d 1839, 1846 (Fed. Cir. 1992). Generally, the disclosure of the patent cited in support of the double patenting rejection cannot be used as though it were prior art. Id. In particular, the Federal Circuit has held that an obviousness-type double patenting rejection involves two inquiries: first, is the same invention claimed twice, and second, if not, does the pending claim define merely an obvious variation of the patented claim. In re Goodman, 29 U.S.P.Q.2d 2010, 2016 (Fed. Cir. 1993).

In the present case, the Examiner has not established a prima facie case of obviousness-type double patenting because the Examiner has not compared the claims of the Kawamura'273 Patent to the claims of the present application. However, to facilitate prosecution, Applicant provides such a comparison in the Tables that follow.

Table 1

Claim 1 of the Present Application	Claim 1 of the Kawamura'273 Patent
1. A no-needle blood access device for hemodialysis comprising: an elongated metallic body, the body being provided at an upper surface with a recess, a periphery of the recess being formed with a peripheral wall defining a well therein; [body is not cylindrical and there is no pipe member]	A no-needle blood access device for hemodialysis comprising: a cylindrical external body, the external body including a peripheral wall and a bottom wall and opens to a top portion, a lower portion of the external body being provided with openings at locations diametrically facing with respect to each other, a pipe member being mounted respectively on each one of the openings, each of first and second artificial conduits being fitted into one of the pipe members, each of the first and second artificial conduits being anastomosed to a targeted artery or vein; [No metallic body]
No columnar internal body.	a columnar internal body fitted into the external body so as to be rotated in the external body, the internal body being provided with a first through-hole diametrically extending through the internal body in the horizontal direction at a location having a height similar to a height of the locations of the openings on the external body;
	the internal body being provided with a second through-hole extending between a first position spaced at an angular distance of α degrees clockwise from the first through-hole in an outer surface of the internal body and having a height substantially equal to the height of the locations of the openings, and a second position spaced at an angular distance of α degrees clockwise from the first through-hole in a top surface of the internal body,
	the internal body being also provided with a third through-hole extending between a third position spaced at an angular distance of β degrees counterclockwise from the first through-hole in the outer surface of the internal body and having a height substantially equal to the height of the locations of the openings, and a fourth position spaced at an angular distance of β degrees counterclockwise from the first

	through-hole in the top surface, wherein $\beta = 180^\circ - \alpha$,
	whereby the device is arranged such that, when the internal body is rotated so that the first through-hole communicates with the openings, the first artificial conduit is in communication with the second artificial conduit through the first through-hole, and when the internal body is rotated so that the first position mates with one of the openings and the third position mates with another one of the openings, the second through-hole is in communication with the second artificial conduit;
a pair of shutters slidably housed within opposed pockets respectively, the pockets being formed at the upper part of the body so that a lower surface of each pocket is flush with the bottom surface of the recess, each of the shutters including a first through-hole respectively formed therein, each of the shutters including a horizontal portion housed within the pocket and a vertical portion formed in the end facing with respect to each other respectively, each of the first through-holes of the shutters being provided at the vertical portion;	No pair of shutters.
a longitudinally extending through-hole disposed in the lower part of the body, each of first and second artificial conduits being fitted into respective ends of the longitudinally extending through-hole, the artificial conduits being disposed for anastomosis with a targeted artery or vein;	
a pair of vertical through-holes disposed at portions of the body each communicating to the respective first through-holes of the shutters when they are opened; and	
a cannula assembly connectable to a dialyzer, the cannula assembly including a pair of cannulas, one end of each of the cannulas being provided with an adapter for mounting the cannula to the body, the adapter being provided with a locking member for preventing the cannula from being removed; [No disk and no first and second pairs of cannulas]	and a cannula assembly connected to a dialyzer, the cannula assembly including: a disk provided with a pair of through-holes at a side-by-side position; a first pair of cannulas connected respectively to one end of one of the through-holes of the disk so as to be in communication with the through-holes of the disk; and a second pair of cannulas connected to the other end of the through-holes of the disk so as to be in communication with the through-holes of the

	disk, whereby each cannula of the first pair of cannulas is inserted into a respective one of the second and third through-holes of the internal body,
whereby the device is arranged such that, when each of the shutters is slid in a direction away from each other, the well is in communication with each of the artificial conduits through the longitudinally extending through-hole and the vertical through-holes of the body and each of the first through-holes of the shutters,	
and when each of the shutters is slid in a direction near to each other, the well is out of communication with each of the artificial conduits.	
	and the internal body rotates in the external body so that the second through-hole communicates with the first artificial conduit and the third through-hole communicates with the second artificial conduit to effect hemodialysis.

Table 2

Claim 13 of the Present Application	Claim 1 of the Kawamura'273 Patent
A no-needle blood access device for hemodialysis comprising: an elongated metallic body, the body being provided at an upper surface with a recess, a periphery of the recess being formed with a peripheral wall defining a well therein; [body is not cylindrical and there is no pipe member]	A no-needle blood access device for hemodialysis comprising: a cylindrical external body, the external body including a peripheral wall and a bottom wall and opens to a top portion, a lower portion of the external body being provided with openings at locations diametrically facing with respect to each other, a pipe member being mounted respectively on each one of the openings, each of first and second artificial conduits being fitted into one of the pipe members, each of the first and second artificial conduits being anastomosed to a targeted artery or vein; [No metallic body]
No columnar internal body.	a columnar internal body fitted into the external body so as to be rotated in the external body, the internal body being provided with a first through-hole diametrically extending through the internal body in the horizontal direction at a location having a height similar to a height of the

	locations of the openings on the external body;
	the internal body being provided with a second through-hole extending between a first position spaced at an angular distance of α degrees clockwise from the first through-hole in an outer surface of the internal body and having a height substantially equal to the height of the locations of the openings, and a second position spaced at an angular distance of α degrees clockwise from the first through-hole in a top surface of the internal body,
	the internal body being also provided with a third through-hole extending between a third position spaced at an angular distance of β degrees counterclockwise from the first through-hole in the outer surface of the internal body and having a height substantially equal to the height of the locations of the openings, and a fourth position spaced at an angular distance of β degrees counterclockwise from the first through-hole in the top surface, wherein $\beta = 180^\circ - \alpha$,
	whereby the device is arranged such that, when the internal body is rotated so that the first through-hole communicates with the openings, the first artificial conduit is in communication with the second artificial conduit through the first through-hole, and when the internal body is rotated so that the first position mates with one of the openings and the third position mates with another one of the openings, the second through-hole is in communication with the second artificial conduit;
a pair of shutters slidably housed within opposed pockets respectively, the pockets being formed at the upper part of the body so that a lower surface of each pocket is flush with the bottom surface of the recess, each of the shutters including a first through-hole respectively formed therein, each of the shutters including a horizontal portion housed within the pocket and a vertical portion formed in the end facing with respect to each other respectively, each of the first through-holes of the shutters being provided	No pair of shutters.

at the vertical portion;	
a longitudinally extending through-hole disposed in the lower part of the body, each of first and second artificial conduits being fitted into respective ends of the longitudinally extending through-hole, the artificial conduits being disposed for anastomosis with a targeted artery or vein;	
a pair of vertical through-holes disposed at portions of the body each communicating to the respective first through-holes of the shutters when the shutters are opened; and	
a cannula assembly connected to a dialyzer, the cannula assembly including a pair of cannulas, one end of each of the cannulas being provided with an adapter for mounting the cannula to the body, the adapter being provided with a locking member for preventing the cannula from being removed; [No disk and no first and second pairs of cannulas]	and a cannula assembly connected to a dialyzer, the cannula assembly including: a disk provided with a pair of through-holes at a side-by-side position; a first pair of cannulas connected respectively to one end of one of the through-holes of the disk so as to be in communication with the through-holes of the disk; and a second pair of cannulas connected to the other end of the through-holes of the disk so as to be in communication with the through-holes of the disk, whereby each cannula of the first pair of cannulas is inserted into a respective one of the second and third through-holes of the internal body,
whereby the device is arranged such that, when each of the shutters is slid in a direction away from each other, the well is in communication with each of the artificial conduits through the longitudinally extending through-hole and the vertical through-holes of the body and each of the first through-holes of the shutters,	
and when each of the shutters is slid in a direction near to each other, the well is out of communication with each of the artificial conduits; and	
wherein the device is disposed so that, when in use, the peripheral wall passes through the skin, and the shutters are disposed at least partially outside the plane of the skin.	Does not recite this relationship between the shutters and the skin when the device is in use.
	and the internal body rotates in the external body so that the second through-hole communicates with the first artificial conduit and the third through-hole communicates with the second artificial conduit to effect hemodialysis.

As evident from Tables 1 and 2, claims 1 and 13, respectively, of the present application are substantially different from claim 1 of the Kawamura'273 Patent. More specifically, claims 1 and 13 of the present invention recite a "metallic body" and a "pair of shutters," which are not recited by claim 1 of the Kawamura'273 Patent. Furthermore, claim 1 of the Kawamura'273 Patent recites a "cylindrical external body" and a "pipe member" that are not recited by claims 1 and 13 of the present application. Claim 1 of Kawamura'273 Patent also requires two bodies, namely, a "cylindrical external body" and a "columnar internal body fitted into the external body so as to be rotated in the external body." However, present claims 1 and 13 recite an "elongated metallic body," but they do not recite a second "body." With respect to the cannula assembly, claims 1 and 13 of the present application do not recite a "disk" and a "first pair of cannulas" and a "second pair of cannulas" as recited by claim 1 of the Kawamura'273 Patent. With respect to claim 13 of the present application, claim 1 of the Kawamura'273 Patent does not recite a relationship between shutters and the skin when the device is in use.

The Examiner contends that "[v]alves are known from everyday life to perform the function of opening and closing, and the instant application merely substitutes one valve for another equivalent valve to perform the known function" (Office Action, dated March 27, 2008, at 4, line 31, to 5, line 3). To the extent that the Examiner is taking "Official Notice" regarding what is well-known in the art, Applicant objects on the grounds that the "valve" alleged by the Examiner is not well-known in the art. The Examiner must now provide "substantial evidence" (e.g., a prior art reference) demonstrating that the alleged "valve" is well-known in the art and also show how it can be combined with the subject matter of claim 1 of the Kawamura'273 Patent to render obvious the subject matter of Applicant's claims 1 and 13, or the Examiner must withdraw the obviousness-type double patenting rejection.

See, e.g., In re Lee, 61 U.S.P.Q.2d 1430, 1434 (Fed. Cir. 2002).

Moreover, the Examiner has refused to compare the claims of the present application to the subject matter of claim 1 of the Kawamura'273 Patent as is required when asserting an obviousness-type double patenting. General Foods Corp. v. Studiengesellschaft Kohle mbH, 23 U.S.P.Q.2d at 1846. Instead, the Examiner is comparing the subject matter of the Kawamura'273 Patent to the "gist" or "heart" of Applicant's invention as evident from the Office Action, dated March 27, 2008, at 4, line 23, to 5, line 3, because the Examiner is comparing the subject matter of claim 1 of the Kawamura'273 Patent to a summary of what the Examiner considers is the invention and not to Applicant's claimed invention as set forth in claims 1 and 13. The Federal Circuit, however, has ruled that the claims define the invention—there is no "gist" or "heart" of the invention. Vas-Cath v. Mahurkar, 19 U.S.P.Q.2d 1111, 1118 (Fed. Cir. 1991).

In view of the above, Applicant objects to the Examiner's insistence on impermissibly comparing the subject matter of claim 1 of the Kawamura'273 Patent to the "gist" or "heart" of the invention and the Examiner's refusal to acknowledge that when Applicant's invention, as recited by independent claims 1 and 13, is compared to the invention claimed by the Kawamura'273 Patent the inventions are not obvious as demonstrated by Tables 1 and 2 above.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness-type double patenting against claims 1 and 13 of this application over claim 1 of the Kawamura'273 Patent.

III. CONCLUSION

The Section 102(b) rejection standing against independent claims 1 and 13 is untenable and must be withdrawn because the Kawamura'541 Patent does not teach, or

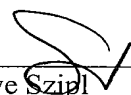
suggest, "a pair of shutters... each of the shutters including a through-hole respectively formed therein" as recited by the claims. In addition, the Examiner has failed to establish a prima facie case of obviousness-type double patenting against claims 1 and 13 of the above-captioned application over claim 1 of the Kawamura'273 Patent because, as shown by Tables 1 and 2 above, the claims are substantially different such that the same invention is not claimed twice and such that the claimed inventions are not obvious in view of one another.

For all of the above reasons, claims 1, 3, 7, 8, 10, 11, and 13 are now in condition for allowance and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below signed attorney for the Applicants.

Respectfully submitted,

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